mayo

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Office of Government Relations

May 22, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fisher's Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. OOD-1033

On behalf of Mayo Foundation, I am submitting the following comments from staff of the Mayo Clinic, relating to the Draft Guidance for Industry entitled "Information Program on Clinical Trials for Serious or Life-threatening Diseases: Establishment of a Data Bank."

Terminology

The term "data bank" implies that results and patient responses will be included as guidance for clinicians in diagnostic or treatment procedures. The actual use is solely as a repository for information about trials seeking enrollment, and is intended to inform the patient and the public about trials being conducted for specific diseases. Outcome data will not reside in this 'data bank". We therefore suggest the name should be "Clinical Trials Registry" or "Clinical Trials Clearinghouse".

Public Input

The repository will be valuable in informing the public of such clinical trials. The repository ought to include an avenue for public input as well. This input could be a valuable indicator of potential problems that can affect enrollment, acceptance, or utilization of a drug following approval. It should not be used as a recruitment device, however. The information in the repository should be crafted similarly to the language in the informed consent, in that it must reach a lay audience.

Sponsor Responsibility

Since the sponsor of the trial stands to benefit from increased enrollment rates, the sponsor should be responsible for handling inquiries about enrollment, not the Federal government. Prospective patients must be made aware very early that the evaluation of the eligibility criteria is the responsibility of the participating investigator, in conjunction with the sponsor, and that rejection may be a function of the clinician's professional judgement as well.

Experimental Procedures

It would be useful to have the repository include experimental procedures as well as experimental drugs.

Voluntary Inclusion

An avenue for voluntary inclusion of non-IND studies would be helpful, for example, trials sponsored by an academic institution seeking patients or colleagues as secondary investigators.

Links to Other Sites

The repository should have links to other sites pertaining to the particular clinical indication being studied. Patients who are searching for help will benefit from other resources.

Thank you for the opportunity to comment on this proposal.

Sincerely,

Bruce M. Kelly

Bruce M. Kelly
Director of Government Relations

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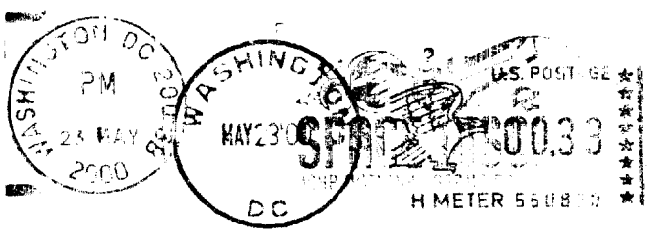

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